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13. ABSTRACT (Maximum 200 Words)

12a. DISTRIBUTION / AVAILABILITY STATEMENT

The goal of the Simulation Technologies for Advanced Trauma Care (STATCare) project is to save lives and improve patient outcome through improved initial and sustainment training for emergency medical care. The STATCare Trauma Patient Simulator TPS) is an interactive, VR-based simulator that offers realistic practice to the trauma-care provider. The system presents the user with a 3D visual and aural scenario in which a trauma incident has occurred. TPS takes the user through the sequence of trauma-patient assessment, beginning with entering and sizing up the scene, determining level of consciousness, checking the ABCDs, and attending to major life-threatening conditions. Physiological information gives the user insight into the events that follow treatment or failure to take appropriate action. Physiological responses to bleeding, pain, internal trauma, and hypoxia are realistic and can be modified by interventions. TPS records all user interactions for post-session review, along with the pertinent physiological data. The technical goals are to fill in the remaining technology holes, mature the technology developed under prior funding, and develop dual-use features. The business goal is to capitalize on a successful strategic alliance between the developers and to launch a commercial product into the emergency medical training market with the cooperation with a major publisher of medical training materials. At this midterm juncture, there are no engineering or scientific conclusions to be drawn, other than the TPS commericalization effort is progressing and proceeding according to plan.

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### 1. Introduction

The Simulation Technologies for Advanced Trauma Care (STATCare) project is based medical training concepts and technologies previously developed to a level of feasibility demonstration. Under prior funding, RTI and our partner, Advanced Simulation Corporation (AdvSim) developed a highly successful demonstration of the Trauma Patient Simulator (TPS). The TPS development effort solved major technical problems associated with combining physiological models with virtual humans for emergency medical training using personal computer (PC) platforms. The goal of achieving realistic patient responses to a limited number of trauma events and trauma treatment procedures on a PC platform was met.

TPS is an interactive, VR-based simulator that offers realistic practice to the trauma-care provider. The system presents the user with a 3D visual and aural scenario in which a trauma incident has occurred. The user may freely navigate within the scene and view the scene and patient from any position. TPS demonstrates the breadth of capabilities that is obtainable by combining real-time simulation, three-dimensional (3D) visualization, virtual reality (VR), multimedia, human-machine dialog, and text on a low cost, Microsoft™ Windows-based PC platform.

The overall goal of the current program is to save lives and improve patient outcome through improved initial and sustainment training for emergency medical care. The technical goals are to fill in the remaining technology holes, mature the technology developed under prior funding, and develop dual-use features. The business goal is to capitalize on a successful strategic alliance between the developers (RTI and AdvSim) and to launch a commercial product into the emergency medical training market with the cooperation with a major publisher of medical training materials.

## 2. Body

## 2.1 Progress by Task in Statement of Work

The specific aim is to develop a product prototype Trauma Patient Simulator capable of realistic simulations for training of military and civilian medical personnel. The technical approach of the project is more evolutionary than developmental, with a strong focus on quality, assessment, and refinement, yet with a degree of innovation and development aimed at meeting market needs. Progress on the current work is presented below according to the proposed statement of work.

### Task 1. Achieve Additional Realism in Trauma Patient Simulation

### Casualty visualization and animation

#### **PROPOSED**

The proposed work will augment the learning value of the virtual environment by adding to the visual and aural realism of the scene, patient, and medical materiel. This includes

animating the patient (e.g., breathing, arterial bleeding, eye movement,), animating procedures (e.g., head tilt), and improving interactions with medical devices.

Several viewers of the TPS have expressed need for improved representations of arterial bleeding. These include visualization of active, pulsatile bleeding and provision of pressure points, tourniquet, and use of the blood-pressure cuff to reduce bleeding. We will create subcutaneous targets for pressure points, and also create targets for heart sounds, breath sounds, and ECG electrodes.

We have experimented with different methods of representing bandages, and we will convert the current ones and all new ones to 3-D objects. We will also develop bandages that have time-varying blood stains that depend on the effectiveness of homeostasis.

#### COMPLETED

Changes in the scenario database have been made to permit greater realism in the trauma scene, including specification of the background setting, cultural scene objects, time of day, weather conditions, and setting, weather, and activity sounds.

Several of the medical device models were edited and several new models were developed. The new medical device models include a physiological monitor, ECG electrodes and lead set, blood pressure cuffs for both the right and left upper arm, and pulse oximeter sensors for both the right and left hand.

The Virtual Reality rendering engine has been enhanced to include an "orbit navigation" mode to ease navigation "around" the patient. The VR engine is also being modified for better interaction with medical devices, texture animation, key-frame object animation, full-screen and dual-screen VR displays, and other user interface improvements.

## Additional virtual human modeling

#### **PROPOSED**

At present only one virtual patient is available, a young, adult Caucasian male. The STATCARE team recognizes the need for patient simulation across a wide variety of ages and ethnic origins for both genders. Whether a new virtual model is developed from scratch or an available COTS 3D model is modified for TPS, the graphical processes for 3D human model development is tedious and costly.

Based on the development costs of the animated male model, we will endeavor to complement our existing male model with a female model with an equivalent set of injuries and animations. The issue of ethnic origin and age will be set during the SME workshops, taking into consideration COTS software models that are available. The virtual human development priority, however, is a completed male model.

#### COMPLETED

Work has focused on improving the existing male model. Re-sculpting of the 3-D model has been done to minimize visualization problems caused by interaction of the closely

spaced body and clothing models. The skin texture has been improved for a more lifelike appearance, and the clothing has been camouflaged to improve its realism. The male model is being enhanced with eye movement and alternative head positions for airway opening procedures.

Additional work has focused on improving the injury representation for existing male model. A variety of injuries were added including stab wounds to the chest and abdomen, and additional scraps and bruises to the face and scalp.

### Casualty-caregiver dialog

#### **PROPOSED**

Patient responses to caregiver questions and commands and will be revised and extended. Given a new, wider range of emotional states for the patient, we can include more varied and realistic responses to caregiver questions. We can also include spontaneous vocalizations and those caused by physical manipulations (i.e., moans and screams, either unprovoked or those caused by manipulating the patient in an area that hurts). We intend to solicit experienced caregiver input for this step.

#### COMPLETED

No progress to date.

### Task 2. Refine Technologies

#### Physiological modeling

#### **PROPOSED**

The proposed work will assess the quality of the physiological simulations and make necessary improvements. We will augment the available trauma and treatment models to include burns, inhalation injuries, and various resuscitation fluids and blood substitutes. In addition, bleeding rates are assigned to each injury as part of the scenario setup, and continue at a constant rate until a bandage or appropriate other intervention is applied. Linking the bleeding rate to blood pressure and blood volume would enhance the scenario accuracy and realism. MRMC research in this area may provide useful insights into the BP-bleeding relationship.

The physiological model already contains numerous pharmacokinetic models for common drugs used in the operating room. Adding a model for carbon monoxide (CO) inhalation will allow creation of a smoke-inhalation scenario that further enriches the training environment. The developers of TPS have extensive experience with the CO modeling, especially the reduced versions used in MIL-HDBK-759A:

#### COMPLETED

A subcontract to Advanced Simulation Corporation (AdvSim) was executed on 22 December 1999. Ken Starko of AdvSim visited RTI on 17 December to discuss the

status of the current physiological models, improvements made by AdvSim during the last year, and proposed improvements for trauma care.

The following improvements are planned:

- Augment the existing chest injury models (e.g., pneumothorax, hemothorax, cardiac tamponade) with an appropriate set of treatment models (e.g., chest decompression, pericardiocentesis). Include physical models for the treatment devices (i.e., chest tube) and allow for failure of such devices
- Integrate AdvSim's newly-developed three body-compartment fluid model. This
  model includes transport of fluid constituents (e.g., electrolytes, pH) and can
  accommodate pathophysiology causing IV fluids to "leak" from the intravascular
  space to the tissue spaces.
- Make our level of consciousness model dependent on brain O<sub>2</sub> deficit, anesthetic
  agents, and blunt cerebral trauma rather than simple mean arterial pressure.

The body fluid model is a necessary first step toward development of burn models and support of various resuscitation fluids and blood substitutes. Further work on burn and carbon monoxide models will be deferred until a publishing partner is acquired.

A consultant agreement was initiated with Dr. Michael McCartney to assist in improving the physiological meta model. The following tasks were initiated:

- Develop an object-oriented database to represent the body anatomy
- Develop a connectivity model to propagate effects of traumatic injury from the organ sustaining injury to dependent anatomical structures
- Specify the relationships of the revised meta model to the physiology models.

### Integrated courseware

#### **PROPOSED**

The proposed work will expand the trauma protocol skill set available in the current TPS, increase the number and variety of "pop-up" procedure demonstrations, and provide context-sensitive links to available military and civilian web-based emergency care reference and training materials.

Pop-up instructional material and videos will be integrated using medical content provided by the Army or taped by RTI in corporation with CEM or other parties. AMEDD representatives will be asked to identify sources of relevant training and reference material available for distance learning via the world wide web. These links will then be added to the protocol database for context-sensitive access to such material.

#### COMPLETED

The context-sensitive help system was updated to reflect changes made to the user interface over the last year. In addition, a tutorial was developed to introduce the novice user to the TPS user interface and to provide assistance during a trauma simulation. It is expected that all of these facilities will be revised later in then project.

## Task 3. Mature the Technology and Sustain Quality (RTI IR&D funding)

### Subject matter expert workshops

#### **PROPOSED**

The STATCARE Team has gained great efficiencies in the current development of TPS through coordinated inputs of Subject Matter Experts. Involving SMEs early and throughout subsequent development phases insures that the people who eventually use the product in day-to-day application have their requirements inherently integrated into the TPS prototype.

A two-day workshop will held at RTI to include military and civilian emergency medicine personnel to review the current status of the TPS and guide development of the product prototype. These workshops will be structured to sharpen the product specification and quality characteristics that have most value to those audiences. In order to build a prototype correctly, structured effort must be devoted to getting the specifications right at the beginning, and these workshops are the right vehicle for doing so.

#### COMPLETED

Our initial Subject Matter Expert workshop was held 12 October 1999 with Gregg Margolis, Associate Director of Education at the Center for Emergency Medicine. As co-author of the National Standard Paramedic Curriculum, Gregg's input is crucial to the success of the STATCare TPS in the civilian sector.

Significant initial suggestions were:

- Scene survey is important, add "problem" with each scene
- EMT's testing assumes a helper, add second pair of hands
- Stress NREMT practical exam in scenario design
- Reduce complexity of interactions to simpler body model
- Improve representation of internal organ injuries

Preliminary meetings were held with military medical experts at two sites to determine their possible collaboration as Subject Matter Experts or as testbeds for the STATCare TPS. These were (1) the National Capital Area Medical Simulation Center (NCAMTC) and the Joint Special Operations Medical Training Center (JSOMTC) at Ft. Bragg NC.

At the NCAMTC, Dr. Kaufmann and his staff were shown the alpha version STATCare TPS and a preliminary version of a Virtual Standardized medical Patient (VSP). Dr. Kaufmann expressed an interest in both training applications, however details on specific working arrangements were not discussed.

JSOMTC staff visited RTI for demonstration of the STATCare TPS and other training applications developed at RTI. This was followed by a visit by RTI staff to JSOMTC to witness evaluation of JSOMTC students in multiple-trauma patient assessment and trauma care with moulaged-actors. During these visits it was determined that the STATCare TPS will go a long way in meeting the training needs of the JSOMTC,

however JSOMTC training differs significantly from civilian EMT-P, military MOS 91B, and military MOS 91W training. JSOMTC staff can provide SME information, but further development of TPS models, protocols and software will be necessary to sufficiently meet their training requirements so that the STATCare TPS would be useful to (and used in) their training regimen.

### Software development life cycle

#### **PROPOSED**

A Software Development Life Cycle (SDLC) is an organized set of activities to capture requirements, verify and validate the TPS prototype, control the development process, and release the TPS prototype to its next development stage with the maximum assurance that TPS meets its specified requirements.

The TPS SDLC will be tailored to the specific needs of the project from the STATCARE Team's existing ISO-9001 compliant Quality Management System. In particular, the SDLC will incorporate appropriate quality and standards requirements expressed in the military and civilian sectors. In the civilian world, the SDLC will be tantamount to the development processes specified by the US Food and Drug Administration's Current Good Manufacturing Practice (CGMP), 21 CFR 820.

Incorporated into the Software Development Life Cycle will be a thorough treatment of a formal Release Management System for TPS software. Included will be procedures for Configuration Management, bug fixing, logging problems identified orally or in writing from our SMEs, working off the bug list through a documented Corrective Action Procedure, and release management with descriptions and risk-based, hierarchical analyses of remaining issues.

#### COMPLETED

The STATCare project is being conducted under the guidelines of RTI's ISO-9001 Quality Management System. STATCare was reviewed as part of RTI's semi-annual ISO-9001 Surveillance Audit of March 20-22, 2000 and passed without comment.

To further support quality software development, we have done the following:

- Prepared a ISO-9001-compliant Project Plan
- Implemented a document revision control system
- Implemented a software revision control system
- Implemented a release management system
- Implemented a corrective actions control system
- Implemented a monthly internal project review
- Prepared a Requirements Traceability Matrix
- Implemented a software distribution build document
- Prepared a virtual reality software interface document

### Prototype evaluation

#### PROPOSED

The particulars of prototype validation must be set during the development life cycle, but the particulars may include educational outcome validation, software ease of use, detailed feature demonstration to a community of users with statistical measurement of effectiveness, validation of portability of the TPS prototype to a different medical scenario, confirmation of publication acceptability, and extensibility to a product release. This step of prototype validation will authoritatively answer the question of whether the right product was built.

Two prototype TPS systems will be set up at an Army designated site using GFE, and two at the Center for Emergency Medicine in Pittsburgh, for a structured evaluation by the user community. RTI will develop data collection forms for the particulars of prototype validation and instruct the participants on the use of the system and of the validation process. Each validation group will have 60 days to conduct the evaluation, and then be left free to use the system in their educational regimen.

#### COMPLETED

A dedicated test system was acquired at RTI for pre-release prototype evaluation.

A second test system was acquired and installed at the Center for Emergency Medicine in Pittsburgh in November 1999 and two members of the CEM staff were trained. CEM plans to assign EMT paramedic students to TPS training beginning in January 2000.

The Assistance Agreement specifies that the military test site shall be the Institute for Surgical Research at Fort Sam Houston. Discussions with the COR indicated that one or two alternative sites may be specified, however a decision on the alternative site(s) for military evaluation of the STATCare TPS has not been made. As this affects the project deliverables, a decision must be taken by the COR and, if necessary, a contract modification made during the third quarter to meet the contract schedule.

The JSOMTC at Fort Bragg is an ideal candidate as their personnel are trained and certified as paramedics according to the NREMT standards. Furthermore their close proximity will allow frequent interaction with low-cost travel for either party. We also would like to reestablish our interaction with the ISR at BAMC, provide them with updated software, and follow up with a site visit later in the project.

Staff at the Center for Emergency Medicine in Pittsburgh received an alpha version of the STATCare TPS in mid March 2000. A review of the alpha TPS user interface and design features by the CEM SMEs identified a number of problems and design issues that would require revision. Accordingly, the TPS Requirements Traceability Matrix was updated and a plan for completing the revisions was developed.

## Task 4. Extend the TPS to Dual-Use (RTI IR&D funding)

## Expansion of cultural objects, clothes, and scenes

#### **PROPOSED**

The VR scenes presently include a European village square, a coastal highway, a kitchen, and a battalion aid-station tent. These scenes will be supplemented with a hospital ER bed bay, a suburban street corner, a construction site, and a farm scene. A variety of military and civilian cultural objects (e.g., tanks, vehicles, construction equipment) will be made available for scene design. We will also obtain recordings of event, environmental, and cultural activity sounds that are consistent with the scenarios.

The patient in TPS has a single set of clothes, which is military garb, and which has no blood stains. We will design two sets of civilian clothing with bloody sections that are consistent with the selected injuries. The military clothing is in four pieces, however, the civilian clothing will be created in smaller increments for more realistic removal and ease of association with injuries.

#### COMPLETED

The following settings have been improved or created:

village square

highway

kitchen

aid-station tent

farm

building construction site

suburban street

forest

Three sets of civilian clothes for the male model were developed. The military outfit was revised to better fit the male model and to improve the camouflage. A database structure to support multiple sets of clothing, with each item comprising multiple pieces for removal, was completed. Cutting each set of clothing into pieces and employing the new clothing database is not yet complete.

A variety of sounds for scenario activity, weather, and event simulation was acquired, reviewed, and added to the database.

#### Scenario studio development

#### **PROPOSED**

A graphical "Scenario Studio" program will be developed to facilitate 3D scenario composition and interactive specification of both graphical and physiological attributes of the trauma casualty body components. Scenario Studio will allow the designer to build scenarios from sets of menus for patient type (sex, age, ethnicity, body habitus, etc.), available injuries, accident event and environmental sounds, the accident scene, and medical or physiological initial conditions and calamities.

Automation of these scenario-assembly tasks will greatly reduce the time required to disseminate new features into existing and new products. In addition, separation of the scenario elements into well-defined modules can streamline the production process by allowing the creation of independent elements by different individuals.

#### COMPLETED

Phase 1 of the Scenario Studio software has been completed. A user interface was designed comprising an "Explorer-like" hierarchical object tree, a database data forms window, and an interactive 3-dimentional modeling window. This includes constructing a "scene graph" comprising scene setting, scene objects, scenario objects, weather conditions, sounds, and time of day. It also includes selecting casualties from the list of pre-defined injured bodies and design-mode visualization of the 3D scene.

To realize the benefits of Scenario Studio, a revised virtual reality engine was developed. This VR engine supports arbitrary placement and orientation of objects for more flexible scene visualization, and interactive medical devices and scene objects. It also supports a hierarchical scene graph for object reuse and so that multiple patients may be placed in the trauma scene (when the computing power becomes available). The improved VR engine is being tested and will be integrated in the TPS beta version.

Phase 2, casualty development, will be deferred until a publishing partner is acquired. For now, casualty development will continue via unaided database editing.

### Scenario development

#### **PROPOSED**

The prototype TPS will comprise ten scenarios. Because a scenario can have a variety of randomly occurring events (e.g., myocardial infarction, blocked airway, internal bleeding), each scenario can have multiple outcomes. A set of ten scenarios can then provide a much larger number of challenges for the caregiver. To support civilian and military certification requirements, the scenarios will be designed for compatibility with the trauma station component of the EMT national registry exam (NREMT) and the Expert Field Medical Badge Test (Army).

### COMPLETED

To support civilian scenario development, over 10 hours of trauma cases have been recorded from The Learning Channel cable television shows "Trauma – Life in the ER" and "Paramedics". These videos contain a wealth of visual, aural, and emotional examples of various trauma and trauma scenes. During the second quarter, we will use these data to suggest a set of civilian trauma cases to the CEM subject mater experts for their consideration and recommendation. We need to identify military subject matter experts to collaborate in the development of equivalent military scenarios.

Thirteen scenarios were developed for testing and demonstrating the alpha version of the software. There scenarios are not complete, rather they were developed to a level sufficient to test various aspects of the TPS database and software implementation. Specification and implementation of the final scenarios will be completed later.

#### The test scenarios are as follows:

name	description	Scene	military
Ambush	Call for medic	Village square	Yes
Crash	A bus has crossed the center line on a coastal highway. A vehicle skids and overturns. 9 1 1 is called.	Bus/car crash on highway # 1	No
Dinner was served	A person calls 9 1 1	Kitchen (tile)	No
Explosion	An explosion has occurred. One casualty is found.	Construction site	No
Farm accident	A farm hand calls 9 1 1 reporting that a farm hand is hurt	Farm with Gator Med Bed	No
Healthy person	Feeling fine	Kitchen (hardwood)	No
Home intruder 1	A homeowner calls 9 1 1 reporting gunshots next door. Arriving at the scene, you find a person in the kitchen.	Kitchen (hardwood)	No
Home intruder 2	A homeowner calls 9 1 1 reporting gunshots next door. Arriving at the scene, you find a person in the kitchen.	Kitchen (hardwood)	No
Home intruder 3	A homeowner calls 9 1 1.	Kitchen (hardwood)	No
Sniper fire 1	After reports of sniper fire, you check the area to locate casualties. Sniper has been eliminated.	Village square	Yes
Sniper fire 2	After reports of sniper fire, you check the area to locate casualties. Sniper has been eliminated.	Village square	Yes
Sniper fire 3	Shots ring out a man is down.	Forest	No
Tutorial	Shots ring out a man is down.	Kitchen (hardwood)	No

## 2.2 Technical or Unexpected Difficulties

We have had no unexpected difficulties so far. The only technical difficulty, not unexpected, is the conversion of our male model for animation using the Direct3D graphics engine. We are making progress toward that end in the VR engine and will experiment with test models in the next quarter.

## 2.3 Deviations from the Original SOW

In Task 2, Refine Technologies, we proposed to refine and extend the physiological models developed by Advanced Simulation Corporation (AdvSim) that are incorporated in the STATCare TPS. This included development of physiological models for burn and inhalation injuries, as well as models for carbon monoxide inhalation exposure.

In discussions with AdvSim, we determined that AdvSim had a newly-developed multiple-compartment body fluid model that could be integrated in TPS for improved fluid

resuscitation modeling. We also determined that integrating this model, along with making necessary revision to the chest trauma models, would consume the available budget for AdvSim.

Fluid resuscitation is an exceedingly important aspect of initial trauma care for patients with blood loss, both on the battlefield and in the civilian sector. This assessment is supported by the recent National Academy Press publication titled "Fluid Resuscitation: State of the Science for Treating Combat Casualties and Civilian Injuries," Institute of Medicine, 1999.

"Historically, 20% of all injured combatants die on the battlefield before they can be evacuated to a field hospital. Blood loss--hemorrhage--is the single major cause of death among those killed in action whose lives might otherwise be saved. Fluid resuscitation and the treatment of hypovolemia (the abnormally decreased volume of circulating fluid in the body) offer the greatest opportunity for reducing mortality and morbidity associated with battlefield casualties. "

We therefore plan on applying the available AdvSim resources to necessary improvements in existing models and implementation of the new body fluid resuscitation model, rather than the other physiology modeling work proposed.

## 3. Key Accomplishments

- Redesign of the user interface to support a full-screen 3-D scene view
- Substantial progress in the development of Scenario Studio
- Bringing the STATCare project under ISO-9001 quality management
- Delivery of TPS alpha disks to CEM and TATRC for test and demonstration
- Completion of Phase 1 of Scenario Studio development
- Completion of set of scene setting models
- Development of an improved VR engine
- Passing ISO-9001 quality management review without comment

## 4. Reportable Outcomes

None

## 4.1 Manuscripts, abstracts, presentations

No formal paper or work was presented in any scientific forum. However, we did have booths at the National Association of EMS Educators 4<sup>th</sup> Annual Symposium in Orlando and at the Medicine Meets Virtual Reality meeting in Newport Beach.. These were very effective forum for showing TPS to leading EMS educators and VR researchers, and for receiving feedback from the EMS education and VR research communities. As before, the overall reaction was very positive with many educators expressing interest in acquiring a TPS system.

We also participated in the TATRC Integrated Research Team meeting.

## 4.2 Patents and licenses applied for/issued

None

# 4.3 Funding applied for based on work supported by this award

Several two-page preproposals were submitted to the National Medical Test Bed (NMTB) request for applications for specialty software modules that would extend the STATCare TPS development. One preproposal was accepted: "Chemical Agent Module for the STATCare Trauma Patient Simulator." A decision whether to submit a full proposal has not yet been determined.

### 5. Conclusions

At this midterm juncture, there are no engineering or scientific conclusions to be drawn, other than the TPS commericalization effort is progressing and proceeding according to plan. An alpha version of the STATCare TPS has been released to the civilian subject matter experts for review, and development of the beta version continues with an expected release date of June 15.